K063637

510(k) Summary

Reliance Medical Systems
1838 E 9800 South
Sandy, UT 84092
Telephone: 801-718-7467
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Contact: Bret M. Berry
Member-Manager

SEP 27 2007

Common or Usual Name:	PEEK or Titanium Bone Fixation Appliance
Proposed Proprietary or Trade Name:	Reliance VBS System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR 888.3060
Product Code:	MQP

Substantial Equivalence
The Reliance VBS is substantially equivalent to the legally marketed Pioneer Surgical Vertebral Spacer (K043206), the Alphatec NOVEL VBR (K042201), the Quantum Vertebral Body Replacement (K050449), the K2M Aleutian Spacer System (K051454), the Medtronic Sofamor Danek Verte-STACK System (K041556, K041452, K040536, K040422, K040167, K031780, K030736, K030735, K030601, K023570, K021791), and the Synthes Vertebral Spacer (K011037, K020152, K024364). The Reliance VBS is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and use with supplemental fixation.

Device Description
The Reliance VBS System is comprised of implant and instrument components. The implant component, the Reliance VBS device, is a spacer, which replaces a portion of the vertebral bodies in the anterior column of the thoracic and lumbar spine. The spacer may be made of PEEK with Tantalum markers, or made of Titanium alloy.

Intended Use/Indications for Use
The Reliance VBS System is intended for use in the thoracolumbar spine (T1-L5) to replace a portion of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture) in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Reliance VBS is designed to restore biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period of time.
The Reliance VBS System is to be used with a legally cleared anterior or posterior supplemental fixation device. Additionally, the Reliance VBS is intended to be used with bone graft.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Reliance Medical Systems, LLC
% Mr. Bret M. Berry
Member-Manager
1838 E 9800 South
Sandy, Utah 84092

SEP 27 2007

Re: K063637
Trade/Device Name: Reliance VBS System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 29, 2007
Received: July 2, 2007

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

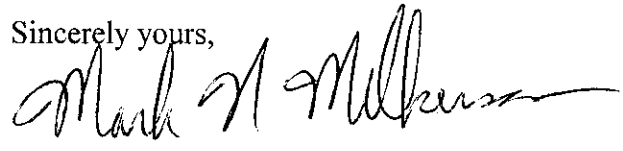
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063637

Device Name: Reliance VBS System

Indications for Use:

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Mark A Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063637

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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